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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/641,376 | 08/14/2003 | Michael S. H. Chu | MIY-P01-027 | 9640 |

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| EXAMINER |
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LUSTUSKY, SARA

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| ART UNIT | PAPER NUMBER |
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3735

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 03/22/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/641,376

Applicant(s)

CHU ET AL.

Examiner

Sara Lustusky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,9-11,13-15,17-22 and 25-29 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37-40 is/are allowed.
- 6) ☒ Claim(s) 1,4,7,12,16,23,24,30,31,36,41,42 and 44 is/are rejected.
- 7) ☒ Claim(s) 2,3,8,32-35,43,45-47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 05/26/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

The Examiner acknowledges Applicant's Amendment dated December 11, 2006. Claims 30 and 31 were amended. New claims 42-47 are acknowledged. Applicant's election of Species II is acknowledged. Claims 1-47 are pending. Claims 5-6, 9-11, 13, 15, 17-22 and 25-29 are withdrawn from consideration.

The Examiner notes that Applicant has failed to use the appropriate status identifiers regarding non-elected claims as required by 37 CFR 1.121(c) and advises Applicant to use appropriate identifiers in future communications with the Office.

Claim Objections

Claim 32 is objected to because of the following informalities: In line 2, the recitation "between the second side of the sling the second side of the sleeve" apparently should read - - between the second side of the sling and the second side of the sleeve - -. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 7, 12, 16 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Green et al. (US 5562689 A).

Green et al. teaches a spacer (20, 100, 150) capable of positioning a portion of a sleeve away from a portion of a sling at least partially enclosed within the sleeve (as described in the abstract) (as seen in Figures 1-6B), wherein the spacer comprises a tube having a lumen or aperture extending therethrough (114, 116), and an anchoring mechanism (20) for anchoring said spacer to the sling (as described in lines 33-52 of column 7), wherein said spacer (20) comprises a handle (300) for facilitating removal of said spacer (20) by a medical operator (as seen in Figure 20), wherein said spacer comprises an engaging member capable of engaging a sleeve for traversal by the portion of the sleeve.

Claims 1, 12, 16, 30-31 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Lund et al. (WO 2002/028315 A).

Lund et al. teaches a spacer (10) capable of positioning a portion of a sleeve away from a portion of a sling at least partially enclosed within a the sleeve, wherein said spacer comprises an engaging member capable of being used for traversal by a portion of the sleeve (as seen in Figures 2a-b, 4b, 8a-11b and 13-18c), further comprising a handle (24C, 34, 54, 76, 132) for facilitating removal of the spacer by a medical operator, wherein the spacer and sleeve are part of a sling assembly comprising a sleeve covering at least a portion of the sling (as described in paragraph [00129] on page 22), wherein said sleeve comprises first and second ends and the spacer (10) is positioned intermediate to the first and second ends, wherein a mid-length portion of the sling is devoid of covering by the sleeve.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 23-24, 41 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neisz et al. (US 6652450 B2) in view of Green et al. (US 5562689 A).

Neisz et al. teaches a sling assembly comprising: a sling (42), a first sleeve (one of 86) having a first end and a second end, a second sleeve (the other of 86) having a first end and a second end (as seen in Figures 9B and 31B), and a clamp, as described above, wherein the second end of the first sleeve and the second end of the second sleeve are fitted into said clamp (as described from line 24 of column 32 to line 36 of column 33). While Neisz et al. teaches that the clamp is used to increase the tension in the sling, the use of a tube shaped clamp is not expressly taught.

Green et al. teaches a sling assembly comprising a sling (12) and a tubular clamp (20, 100, 150), wherein two ends of said sling (12) are fitted into said clamp (as seen in Figures 1 and 4) (as described in the abstract), wherein said claim is used to increase the tension in the sling (as described in line 8-29 of column 3), wherein said clamp can be used as a spacer capable of positioning a portion of a sleeve away from a portion of said sling at least partially enclosed within said sleeve, wherein the interior of said clamp forms a receptacle capable of being used for traversal by the portion of a sleeve and wherein said clamp comprises an insert (122) for mating within said

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receptacle and capable of holding a portion of a sleeve in place within said receptacle (as described in lines 6-35 of column 8), wherein said receptacle is substantially U-shaped (as seen in Figures 5A-6B).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a clamp similar to that of Green et al. as the clamp in a sling assembly similar to that of Neisz et al. in order to increase and maintain the desired tension of the sling during implantation.

Allowable Subject Matter

Claims 2-3, 8, 32-35, 43 and 45-47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 37-40 are allowable over the prior art of record.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 2-3 and 43, none of the prior art of record teaches or fairly suggests a sling assembly comprising a sling, a sleeve having a portion positioned away from said sling by a spacer, wherein the portion of said sleeve that is positioned away from said sling is at least partially enclosed by said spacer.

Regarding claim 8, none of the prior art of record teaches or fairly suggests a sling assembly comprising a sling, a sleeve having a portion positioned away from said sling by a spacer, wherein said spacer is a tube that is anchored by sutures to the sling.

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Regarding claims 32-35, none of the prior art of record teaches or fairly suggests a sling delivery system comprising an elongate sling, a sleeve covering at least a portion of the elongate sling, the sleeve having a portion positioned away from said sling by a spacer, wherein both the sling and sleeve comprise first and second sides and wherein said spacer is disposed between the second side of said sling and the second side of said sleeve.

Regarding claims 37-40, none of the prior art of record teaches or fairly suggests a sling system comprising a sling, a sleeve comprising a first side having first and second slit-shaped apertures and a second side, wherein said sling threads out of the sleeve through said first slit-shaped aperture and back into the sleeve through said second slit-shaped aperture thereby creating a mid-length sleeve loop, and a spacer positioned to space the sling away from the mid-length sleeve loop.

Regarding claim 45, none of the prior art of record teaches or fairly suggests a sling assembly comprising a sling, a sleeve having a portion positioned away from said sling by a spacer, wherein said spacer has first and second sides, is closed along a top edge and open along first and second intermediate edges, and wherein the portion of said sleeve is at least partially enclosed between the first and second sides.

Regarding claim 46, none of the prior art of record teaches or fairly suggests a sling assembly comprising a sling, a sleeve having a portion positioned away from said sling by a spacer, wherein said spacer has first and second sides, a bottom edge that is bonded together and to a section of the portion of the sleeve, and wherein the portion of said sleeve is at least partially enclosed between the first and second sides.

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Regarding claim 47, none of the prior art of record teaches or fairly suggests a sling delivery system comprising an elongate sling, a sleeve covering at least a portion of the elongate sling, the sleeve having a portion positioned away from said sling by a spacer, wherein said spacer at least partially encloses the portion of the sleeve.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Benderev (US 6050937 A) teaches a tensioning device for use with a sling.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

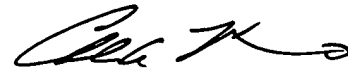
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



S.L.



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